

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender
neutral fictitious names, and ABC
CORPORATION 1 through 10 (fictitious
names).

Defendants.

CIVIL ACTION No. 4:21-cv-10312-FKB-RSW

Hon. F. Kay Behm

**PLAINTIFF TRUTEK'S BRIEF IN OPPOSITION TO DEFENDANT
BLUEWILLOW'S MOTION FOR SUMMARY JUDGMENT**

Stanley H. Kremen
Attorney at Law
4 Lenape Lane
East Brunswick, NJ 08816
(732) 593-7294
shk@shk-dplc.com
Attorney for the Plaintiff

Keith Altman
The Law Office of Keith Altman
38228 West 12 Mile Road, Suite
375
Farmington Hills, Michigan 48334
(248) 987-8929
keithaltman@kaltmanlaw.com
Attorney for the Plaintiff

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Pursuant to Fed. R. Civ. P. 56, Plaintiff/Counter-Defendant, Trutek Corp. ("Trutek"), by and through its counsel, Stanley H. Kremen, Esq., submits its brief in opposition to Defendant/Counter-Plaintiff, BlueWillow Biologics, Inc.'s Motion For Summary Judgment. The stipulated order entered January 23, 2023 extended the page limits for briefs in opposition to summary judgment motions to 40 pages. ECF 55.

I. INTRODUCTION

Fed. R. Civ. P. 56(a) states, "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." However, in this matter, Plaintiff's version of the facts differs substantially from Defendant's version. There is a genuine dispute. Moreover, "courts are required to view the facts and draw reasonable inferences 'in the light most favorable to the party opposing the [summary judgment] motion.'" *Scott v. Harris*, 550 U.S. 372, 377 (2007).¹ "Summary judgment will not lie if the dispute about a material fact is 'genuine,' that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. At the summary judgment stage, the trial judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether

¹ Citing *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962).

there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986).

In its motion, Defendant alleged three issues, the facts of which are disputed by Plaintiff.

1. *Trutek cannot meet its burden to establish that BlueWillow has infringed the claims of the U.S. Patent 8,163,802 ("the '802 Patent").*²
2. *Trutek cannot be awarded any relief for its claims of infringement, injunctive relief, or damages - because BlueWillow is no longer selling the accused product and because Trutek has failed to meet its burden of demonstrating any pre-suit damages, including for the reasons provided in BlueWillow's Motion to Exclude Damages (Dkt. 39).*
3. *Each of the asserted claims of the '802 Patent are anticipated by U.S. Application No. 2009/0143476 ("Baker") when applying Trutek's own infringement theories.*

II. Summary Judgment of Non-Infringement should not be granted because BlueWillow's product NanoBio® Protect infringes claims 1, 2, 6, and 7 of the '802 Patent.

Sometime in early 2021, individuals employed by Trutek discovered that BlueWillow's NanoBio® Protect was being sold at the same online outlets as Trutek's NasalGuard® products and in direct competition with Trutek's products. Examination of the BlueWillow website, www.bluewillow.com, convinced Trutek personnel that the BlueWillow

² Defendant submitted a copy of the '802 Patent as part of an exhibit accompanying its Motion for Summary Judgment — ECF 59-3, PageID 1892 through 1897 (*i.e.* pp 8-13 of 98).

product infringed claims of the '802 Patent. A screenshot copy of the relevant BlueWillow web pages is uploaded herewith as Exhibit 1. The asserted claims of the '802 Patent are claims 1, 2, 6, and 7.

1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
 - a) electrostatically attracting the particulate matter to the thin film;
 - b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
 - c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidal agent, and wherein said formulation, once applied:
 - a) electrostatically attracts the particulate matter to the thin film;
 - b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
 - c) inactivates the particulate matter and renders said particulate matter harmless.

6. The formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride.

7. The formulation of claim 2 wherein the at least one biocidal agent is Benzalkonium Chloride or Lysine HCL.

The contents of the web pages shown in Exhibit 1 represent admissions of a party opponent, and are not precluded from admissibility as hearsay under Fed. R. Evid. 801(d)(2).

A. NanoBio® Protect electrostatically attracts harmful particles (germs) and renders them harmless, satisfying Element (a) of Claims 1 and 2.

In Exhibit 1, BlueWillow states that, "NanoBio® Protect is an alcohol-free antiseptic product that can be used to help *reduce germs on skin that can cause infections.*" It further states, "[t]he product is easy to apply with any cotton swab *for use on the skin around the rim of your nose as well as the skin one-half inch inside each nostril.*" (Ex. 1, Page 1.) Then, "The nano-droplets are *attracted to germs by electro-kinetic charge* and present the BZK³ in such a way to *enable killing of germs on contact,*" (*Id.* at Page 2.)⁴

Thus, BlueWillow's website makes it clear that NanoBio® Protect is a formulation that *electrostatically inhibits* harmful particulate matter (*i.e., germs*) through *nasal inhalation* wherein the formulation is *applied to skin or tissue of nasal passages* of the individual. (Claims 1 & 2.)

B. NanoBio® Protect forms a thin film in the nasal passages having adequate impermeability, thus satisfying Element (b) of claims 1 and 2.

³ BZK is BlueWillow's acronym for benzalkonium chloride.

⁴ Emphasis added.

1. Nanobio® Protect forms a thin film in the users nasal passages.

Now, on page 10 of its brief, Defendant alleges, "NanoBio® Protect does not form a 'thin film' having 'adequate impermeability.'" Dr. Edward Lemmo's⁵ "Opening Technical Report" is submitted herewith as Exhibit 2.

On page 11, he states:

Here, the Nanobio Protect product is a liquid nanoemulsion consisting of nano-droplets that range between 300-600 nanometers in size (Id.). These droplets are extremely small. A nanometer is one-billionth of a meter. When administered to a user's nostrils, the product forms a thin film that adheres to the skin or tissue of his nasal passages. If that were not the case, the liquid would instantly drip out of the user's nose. Instead, "the droplets persist on the skin for four or more hours." Further, the "droplets significantly hydrate skin to avoid dryness and cracking that can allow germs in." Thus the product exhibits impermeability.

In that opinion, Dr. Lemmo provides the logic to show that the NanoBio® Protect product forms a thin film on the skin or tissue of the nasal passages. If a surface (*e.g.*, skin) is wetted by a liquid, the liquid adheres to that surface in a thin film. If that were not so, then the surface would not remain wet. On Page 15 of its brief, Defendant quotes from Dr. Lemmo's deposition (ECF 49-2, at 222:23-1). In his deposition, Dr. Lemmo agreed that, "[b]y their very nature, nanoemulsion droplets exhibit an electrostatic charge which causes them to repel one another." He further agreed that when applied to the skin, the nanoemulsion does not form a

⁵ Dr. Edward A. Lemmo is one of Trutek's expert witnesses.

continuous layer on the skin. It still exists as individual droplets. However, neither claim 1 nor 2 recite that the thin film is continuous. It can be logically deduced that even if the layer of the NanoBio product resembles "Swiss cheese," the product still coats the skin or tissue of the nasal passages as a thin film.

Dr. Lemmo's expert report replying to Defendant's expert report on non-infringement is submitted herewith as Exhibit 3. On page 11 of that report, Dr. Lemmo said:

It is well-known that most harmful particles (including microorganisms) are negatively charged. It is basic physics that there would be electrostatic attraction between the nano-droplets and the harmful particles. Once applied to the skin or tissue of the individual's nasal passages, the nano-droplets remain active in the nose for up to 8 hours. The Nanobio Protect product adheres to the nasal tissue in a thin film. If this were not so, the liquid would immediately drip out. The nanoemulsion becomes impermeable, not allowing "germs to penetrate." The "germs" become in contact with the benzalkonium chloride biocide and are held there long enough to be deactivated and rendered harmless.

2. The NanoBio® Protect thin film exhibits adequate impermeability

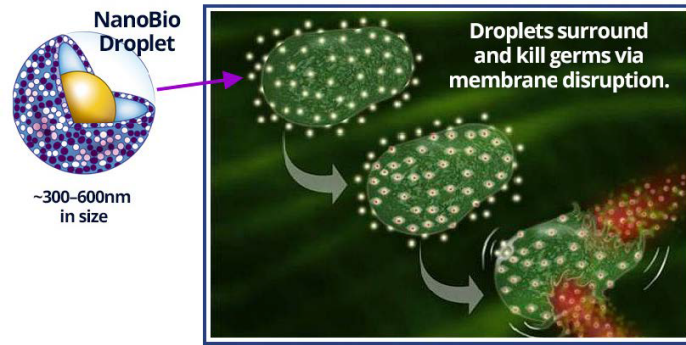
Now, we get to the issue of adequate impermeability. Claims 1 and 2 speak of adequate impermeability in Element (b) *supra*. As such, it is integral to the "hold" function. On page 8 of his expert report submitted on August 23, 2022, Dr. Lemmo said:

Most harmful airborne particles have a negative electrostatic charge. The formulation is applied to the skin or tissue of the nasal cavities as a thin film. The presence of a

cationic agent in the formulation produces a positive electrostatic charge, which attracts and captures the negatively charged particles. A biocide in the formulation would ordinarily be expected to inactivate and kill the captured bioactive particles. But, to be effective, biocidal action requires contact with bioactive particles for a certain time period. If the captured particles happen to dislodge from the formulation's thin film, they would remain active and be inhaled. Even if they were in contact with the biocide for a sufficient time to be inactivated, the dislodged inactivated particles would still be able to be inhaled. Thus the "hold" function is critical to usefulness of the invention.

In its claim construction decision (ECF 53) following the Markman Hearing, this Court stated, "when read in the context of the invention, the term 'adequate impermeability' refers to a part of the technology that allows harmful particulate matter to be held in place long enough to be rendered harmless. It is an expression of the qualities inherent in the thin film that allow the technology to work according to its specification."

Returning to Page 2 of Exhibit 1, the NanoBio droplets (comprising an oil-in-water nanoemulsion) surround the germs, holding them for a sufficient time to render them harmless. The harmful particles are held in place long enough so as to be inactivated.



3. The NanoBio® Protect formulation contains both a cationic agent and a biocidal agent, and benzalkonium chloride serves both functions.

Finally, claim 2 of the '802 Patent recites a formulation containing both a cationic agent and a biocidal agent. Benzalkonium chloride (BZK) is a cationic agent, capable of producing a positively charged electrostatic field. It is also a well-known biocide.

Claim 6 states that the cationic agent of the formulation of claim 2 is benzalkonium chloride (BZK). Claim 7 states that the biocidal agent of that formulation is also benzalkonium chloride.

C. The amount of benzalkonium chloride present in the NanoBio® Protect Product is sufficient to satisfy the claimed functions.

On page 16 of its brief, Defendant alleges, "NanoBio® Protect does not contain a sufficient amount of BZK to satisfy the claimed functions." Defendant stated that "each of the elements of claim 2 "requires the claimed formulation to:

- "electrostatically inhibit [] harmful particulate matter from infecting an individual" (claim preamble);
- "electrostatically attract [] the particulate matter to the thin film" (claim element (a) ("attract" or "catch"));
- "hold[] the particulate matter in place . . ." (claim element (b) ("hold")); and
- "inactivat[] the particulate matter" and "render[] said particulate matter harmless" (claim element (c) ("kill" or "inactivate")).

First, Plaintiff cites Exhibit 1, which contains admissions by BlueWillow under Fed. R. Evid. 801(d)(2).

1. NanoBio® Protect electrostatically inhibits harmful particulate matter from infecting an individual.

The term "electrostatically inhibits" must first be defined. This Court's Claim Construction Opinion and Order dated January 10, 2023, ("Markman Order") ECF 53, at Page 11 stated:

Plaintiff suggested "electrostatically inhibiting" be construed as referring to a "formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped, held thereto, and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless."

Further, at Page 12, the Markman Order stated, "The term 'electrostatically inhibiting' refers to one of the formulation's key functions: using an electrostatic field to trap and neutralize harmful particles. It

references both the electrostatic means by which the formulation operates and the aim of that formulation."

And, finally at Page 15, the Markman Order stated, "[f]or all the reasons stated above, the Court will adopt Plaintiff's construction of the term 'electrostatically inhibiting.'"

Now, on Page 1 of Exhibit 1, in describing the action of NanoBio® Protect, BlueWillow states, "NanoBio® Protect is an alcohol-free nasal antiseptic solution that can be used to help reduce germs on skin that can cause infections." BlueWillow continues, "The nano-droplets are attracted to germs by electro-kinetic charge and present the BZK in such a way to enable killing of germs on contact." *Id.* at Page 2.

Thus, according to the Courts accepted definition of the claim term, NanoBio® Protect electrostatically inhibits harmful particulate matter from infecting an individual.

2. NanoBio® Protect electrostatically attracts the particulate matter to the thin film.

On Page 16 of the Markman Order, the Court stated, "Plaintiff suggested a construction of 'electrostatically attracting' to describe a "formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged airborne particulates (including

microorganisms) in the vicinity of the surface are electrostatically trapped."

Then, it stated, "[t]he Court will adopt Plaintiff's proposed construction because the term 'electrostatically attracting' has a meaning that is clear from the plain language of the patent." *Id.*

As argued *supra*, when applied to the nasal mucosa, NanoBio® Protect forms a thin film on the skin or tissue of the nasal passages. BlueWillow states, "[t]he nano-droplets are attracted to germs by electrokinetic charge," and "[t]he droplets persist on skin for 4 or more hours, enabling long-lasting effectiveness." Exhibit 1, at Page 2. Further, BlueWillow states that, "[t]he nanodroplets are small enough to be effective on the skin, but too large to be absorbed into the bloodstream – creating a layer of lasting protection." *Id.* at Page 7.

Thus, according to the Courts accepted definition of the claim term and BlueWillow's admissions regarding the actions of its product, NanoBio® Protect electrostatically attracts the particulate matter to the thin film.

3. **NanoBio® Protect holds the particulate matter in place by adjusting the adhesion of the thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability.**

BlueWillow admits that the NanoBio® Protect nanodroplets surround germs, and kill them *via* membrane disruption. Exhibit 1, Page 2. As

argued *supra*, by surrounding the harmful particulate matter (*i.e.*, germs) for a period of time long enough to "kill" them, the product satisfies the claimed "hold" function.

On Page 17 of the Markman Order, the Court stated, "Plaintiff argued that 'adequate impermeability' refers to the "thin film holding harmful particles in place and inhibiting them from penetrating the thin film and contacting the skin or tissue of an individual's nasal passages. This is done by varying the concentration of ingredients . . . [,] thereby adjusting the adhesion and cohesion of the thin film." ***This Court adopted Plaintiff's construction of this term.***

BlueWillow stated, "[t]he droplets persist on skin for 4 or more hours, enabling long-lasting effectiveness." Thus, they adhere to the skin or tissue of the nasal passages. Exhibit 1, Page 2. Because, the liquid does not drip out of the user's nose, the product has adequate viscosity (*i.e.*, it is cohesive).

Further, BlueWillow states that, "[t]he nanodroplets are small enough to be effective on the skin, but too large to be absorbed into the bloodstream – creating a layer of lasting protection." *Id.* at Page 7. Thus the layer of lasting protection (*i.e.*, the thin film) is impermeable.

Thus, NanoBio® Protect holds the particulate matter in place by adjusting the adhesion of the thin film to stick to the skin or tissue and by

adjusting the cohesion of the formulation to provide adequate impermeability.

4. NanoBio® Protect inactivates the harmful particulate matter and renders said particulate matter harmless.

Clearly, BlueWillow makes this claim throughout Exhibit 1. BlueWillow claims that the BZK kills germs on contact *via* membrane disruption. Thus, they are deactivated.

5. Verification that the amount of benzalkonium chloride present in the NanoBio® Protect product is sufficient to satisfy the claimed functions.

In its brief, Defendant makes much ado that the ten formulations in the '802 Patent list the amount of benzalkonium chloride in the range of 0.25-1%. This was even confirmed by Dr. Lemmo in his deposition. *See* Defendant's brief, Page 19. Defendant then states, "Trutek cannot credibly argue now, that a product containing only 0.13% BZK will function as required by the '802 Patent asserted claims, given that the amount of BZK is less than half of what is required."

Defendant's argument fails for two reasons. First, Exhibit 1 shows that NanoBio® Protect does indeed function as required by the '802 Patent asserted claims, even though it contains only 0.13% benzalkonium chloride. Second, the ten formulations listed in the specification of the '802 Patent are

merely examples (embodiments) of what is claimed. They are not exclusive. The claims of the '802 Patent do not specify any percentages of ingredients to endow the formulation with effective inhibition of infection from inhalation of harmful particulate matter. Nothing in the patent specification, or in any statements made by Dr. Lemmo (or any of Trutek's experts) set forth that a lesser amount of benzalkonium chloride would be ineffective. BlueWillow has not presented any evidence to show that a formulation containing only 0.13% benzalkonium chloride would be ineffective in performing the functions claimed in the '802 Patent.

During development of its own NasalGuard® products, Trutek regularly makes measurements in its own laboratory that are indicative of the surface electrostatic charge of its products. This is a function of Trutek's quality assurance process. Studies have been performed that confirm the efficacy of Trutek's own products in protecting against infections from airborne microorganisms.

Sometime around January 2021, Trutek personnel purchased specimens of NanoBio® Protect, and tested them as they would Trutek's own products. The results of their experiments demonstrated to Trutek personnel that the surface electrostatic charge is close in magnitude to

Trutek current NasalGuard® products that claim the protection of the '802 Patent.

To confirm its own measurements, Trutek turned to two outside experts,⁶ who independently confirmed that the NanoBio® Protect product exhibited a surface electrostatic charge having the same order of magnitude as Trutek's own NasalGuard® products.⁷

On Page 9 of its brief, Defendant argued, "[t]o establish literal infringement, all of the elements of the claim, as correctly construed, must be present in the accused system." (citing *TechSearch LLC v. Intel Corp.*, 286 F.3d 1360, 1371 (Fed. Cir. 2002).) Plaintiff has shown *supra*, that:

- NanoBio® Protect electrostatically attracts harmful particles (germs) and renders them harmless, satisfying Element (a) of Claims 1 and 2 of the '802 Patent.
- NanoBio® Protect forms a thin film in the nasal passages having adequate impermeability, thus satisfying Element (b) of claims 1 and 2 of the '802 Patent.
- NanoBio® Protect inactivates (kills) the harmful particulate matter and renders said particulate matter harmless, thus satisfying Element (c) of claims 1 and 2 of the '802 Patent.

⁶ Dr. Alexei Ermakov (Director, Chemistry Instruments and Experiments at Rutgers University) and Shane Burns (Test Laboratory Manager of Electro-Tech Systems, Inc., Perkasié, Pennsylvania).

⁷ BlueWillow filed a motion to exclude the testimony of Dr. Ermakov and Shane Burns because its experts disagree with the methodology of Trutek's experts.

- The amount of benzalkonium chloride present in the NanoBio® Protect Product is sufficient to satisfy the claimed functions, thus satisfying claims 6 and 7 of the '802 Patent.

Thus, a genuine dispute exists as to all of the facts material to a determination of whether BlueWillow's NanoBio® Protect product infringes the '802 Patent. Because summary judgment must be decided in light most favorable to the non-moving party, summary judgment of non-infringement should not be granted.

III. Summary Judgment denying damages and/or other remedies should not be granted because Plaintiff is entitled to damages as a matter of law.

In its initial complaint, as part of its Prayer for Relief, Trutek requested the following:

Defendants be required to pay over and account to Plaintiff for all gains, profits, and advantages derived from the infringement of its '802 Patent beginning April 24, 2012, based upon manufacture, sales, and/or use of the NANOBIO products in the United States and anywhere in the world, or by way of international commerce with the United States.

Fed. R. Civ. P. 54(c) states that, "[e]very other final judgment [*other than a default judgment*] should grant the relief to which each party is entitled, even if the party has not demanded that relief in its pleadings."

35 U.S.C. § 284 sets the statutory minimum for a damage award in cases of patent infringement. The damage to be awarded can be "in no

event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court."

On February 18, 2022, Defendant served Plaintiff with interrogatory requests. Defendant's Interrogatory No. 10 requested:

Identify and describe in detail all damages that you seek to recover in this Action, including an accounting of the specific categories of damages claimed (e.g., lost profits, reasonable royalty, or any other category you claim to have suffered as a result of any conduct by BlueWillow), the amount for each category and how it was calculated, the legal and factual bases supporting your claim for damages, all documents and evidence upon which you rely for your calculations, and the persons most knowledgeable about the information requested in this interrogatory.

Plaintiff responded on May 10, 2022 with the following answer to Defendant's Interrogatory No. 10:

The NanoBio Protect product is no longer being sold. BlueWillow took the product off the market sometime in mid-2021. However, the start date and end date of this product's sales is unknown. Because this product infringes upon the '802 Patent, every sale of this product made by BlueWillow should have accrued to Trutek. Therefore, Plaintiff seeks the profit from every sale. The method of calculation of lost profits will be presented by an expert yet to be engaged.

On April 8, 2022, Plaintiff served Defendant with interrogatory requests. Interrogatory No. 11 requested:

For the Nanobio Protect nasal antiseptic product, which is currently cited in Plaintiff's Complaint, list and identify in

detail (a) the entities to which said product was sold; (b) the monetary amount of sales to each entity; (c) the total sales for the product; (d) the unit price of the product sold to each entity; and (e) the cost of each unit sold to each entity.

Defendant served its answers on May 9, 2022. Every page of Defendant's answers to interrogatories were marked with the heading, "OUTSIDE COUNSEL EYES' ONLY." Defendant's answer to Plaintiff's Interrogatory No 11 stated:

In addition to its General Objections, BlueWillow objects to the interrogatory to the extent it seeks information in Plaintiff's possession, custody, or control, including information provided in response to other discovery requests.

Subject to and without waiving its objections, BlueWillow states that NanoBio Protect® was primarily sold directly to customers through Amazon and CVS, in addition to a small volume of sales through other limited distribution channels (small pharmacies and independent websites). Pursuant to Fed. R. Civ. P. 33(d), BlueWillow states that the remaining answers to this interrogatory may be derived or ascertained from business records that BlueWillow will produce upon entry of a protective order.

After close of fact discovery, a court ordered mediation took place on June 14, 2022. Just prior to that event, Defendant's counsel presented Plaintiff's counsel with a document marked, "ATTORNEY'S EYES ONLY." The document was entitled, "BlueWillow Biologics NPB Sales By Month Jan 2020-Mar 2022." ("Defendant's Sales Document") This document was very detailed, and it provided most of the information requested in Plaintiff's

Interrogatory No. 11. However, the information therein could not be shared with anyone from Trutek. There was sufficient information in the document regarding number of sales to enable the fact finder to determine the value of a reasonable royalty. Yet, client input was necessary to determine Trutek's lost profits. At the mediation session, Plaintiff's counsel presented the mediator with an estimate of lost profits, and the mediator was instructed to share that document with Defendant's counsel. But, input from the client was necessary to provide exact information. Defendant's Sales Document still remains unnecessarily classified as "ATTORNEY'S EYES ONLY" to this day.⁸

Defendant's Sales Document shows that even after the lawsuit was filed, Defendant continued to sell its NanoBio® Protect product for approximately two-to-three additional months. At this point, BlueWillow was aware of the '802 Patent as well as Plaintiff's allegations of infringement.

Once having examined Defendant's Sales Document, it became apparent that expert testimony would not be necessary to calculate either Trutek's lost profits or a reasonable royalty. Defendant's Sales Document

⁸ Due to Defendant's designation of the sensitive nature of Defendant's Sales Document, that document will not be uploaded along with this brief.

contained sufficient sales information that lost profits could now be presented as fact testimony by Trutek personnel.

In its brief, Defendant stated that, "Courts will not permit introduction of a damages calculation or theory to be submitted to a jury when disclosed for the first time in response to a motion *in limine* or summary judgment." This is not the case here. Defendant delayed producing its sales information necessary for such calculations until after close of fact discovery. That document contained sufficient information to make royalty calculations. Nothing more was necessary. Further, Plaintiff's counsel gave estimated lost profit calculations for Trutek to the mediator with instructions to provide it to Defendant's counsel.⁹ However, due to the actions of Defendant, Trutek personnel are to this day prohibited from having information regarding the number of units of NanoBio® Protect that were sold, and to whom. It was the Defendant who created the problem by delaying providing sales data to Plaintiff until after close of discovery and by still preventing Trutek personnel from accessing it.

Because NanoBio® Protect is no longer being sold by BlueWillow, it is difficult to understand why BlueWillow feels the need to hide the

⁹ Due to Defendant's designation of the sensitive nature of Defendant's Sales Document, the document estimating Trutek's lost profits will not be uploaded along with this brief because it copies sales information from Defendant's document..

product's sales data from Trutek. It is not expected that release of sales and marketing information for a product no longer on the market would compromise the Defendant. Certainly, a jury will require that information, and it is difficult to conceive that the Plaintiff will be excluded from such testimony.

Defendant further stated, "courts will not award patent damages without supporting evidence or based on mere speculation and conjecture." Based on the information in Defendant's Sales Document, speculation and conjecture will not play a role in the calculation.

Now, on Page 28 of its brief, Defendant states that, "Trutek has not met its burden to prove pre-suit damages." In its answer to Trutek's initial complaint, Defendant's Fourth Affirmative Defense read:

On information and belief, BlueWillow's claim for damages is statutorily barred and/or limited by 35 U.S.C. § 287 as, among other reasons, Plaintiff and/or their prior owners of the asserted patent and/or their agents, representatives, and/or licensees failed to adequately mark patented articles.

Defendant was aware of Trutek's NasalGuard® products and of the patents for which protection is claimed. Yet, Defendant made no effort to inquire, or to collect or present any evidence to shore-up its defense. Nevertheless, the packaging for every NasalGuard® product sold in the United States since 2013 has not only a reference to the '802 Patent marked

thereon, but also reference to several other Trutek owned patents that cover the technology. *Arctic Cat Inc. v. Bombardier Recreational Prod. Inc.*, 876 F.3d 1350, 1366 (Fed. Cir. 2017) held that "[t]he patentee bears the burden of pleading and proving he complied with § 287(a)'s marking requirement." Trutek will show *via* fact testimony that it complied with the marking requirement of 35 U.S.C. § 287. All purchasers of NasalGuard® products in the United States had actual notice that the products sought protection of the '802 Patent.

In his expert report, Dr. Lemmo stated that the "patent number of the '802 Patent is clearly marked for every unit sold in the United States." In addition, Plaintiff's expert, Amirali Y. Haidri, testified that he had purchased Trutek's NasalGuard® product in 2020, and that the '802 Patent was marked on the product's packaging. *See* Defendant's brief, Page 30. Mr. Haidri is an attorney and an officer of the court. At his deposition, Mr. Haidri was under oath. While he did not specify the exact date of purchase, the product's packaging must have been printed some time prior to his purchase. Defendant's Sales Document presents sales figures only dating back to January 2020.

Proof that Plaintiff marked every NasalGuard® product since 2013 can only be shown by fact testimony from a Trutek employee-representative.

Defendant had the opportunity to take a 30(b)(6) deposition, but it declined to do so. Therefore, Trutek will present such evidence to the Court either by request or at trial.

Lastly, should summary judgment be granted denying a damage award to Plaintiff for Defendant's tort of infringing the '802 Patent, or if the court grants Defendant's Motion to exclude damages, the result would be unjust and manifestly unfair, and it would reward BlueWillow for its wrongful acts.

A genuine dispute exists as to all of the facts material to a determination of whether damages were properly pled. Because summary judgment must be decided in light most favorable to the non-moving party, summary judgment of a zero damage award should not be granted.

IV. Summary judgment declaring the '802 Patent invalid should not be granted because Defendant failed to meet its burden of proving invalidity of the asserted claims by a standard of clear and convincing evidence.

Defendant's brief alleges that the asserted claims of the '802 patent are invalid for being anticipated under 35 U.S.C. § 102 by U.S. Patent

Application Publication US 2009/0143476 A1 by Baker, *et.al.* (hereinafter, "Baker '476").¹⁰ First, Plaintiff does not dispute that Baker '476 is prior art.

35 U.S.C. § 282(a) states:

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

Further, "Section 282 requires an invalidity defense to be proved by clear and convincing evidence." *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91 (2011). "Clear and convincing evidence is that weight of proof which produces in mind of trier of fact a firm belief or conviction as to truth of the allegations sought to be established; it is evidence so clear, direct, weighty and convincing as to enable fact-finder to come to clear conviction without hesitancy, of truth of the precise facts of case." *In re. CNC Payroll, Inc.*, 491 B.R. 454 461 (2013), citing *Shafer v. Army & Air Force Exch. Serv.*, 376 F.3d 386, 396 (5th Cir. 2004). See also, *In re. JMW Auto Sales*, 494 B.R. 877, 889 (2013).

¹⁰ Defendant submitted a copy of Baker '476 as part of an exhibit accompanying its Motion for Summary Judgment — ECF 59-3, PageID 1899 through 1982 (*i.e.* pp 15-98 of 98).

Defendant's brief only alleges anticipation under 35 U.S.C. § 102. Obviousness under 35 U.S.C. § 103 is not alleged in its brief. The issue of obviousness of the '802 Patent's claims over Baker '476 is argued in the reports of Amirali Y. Haidri and Dr. Edward A. Lemmo as well as in other briefs and motions pending before this Court. Thus, only anticipation of the '802 Patent's claims under 35 U.S.C. § 102 by Baker '476 will be discussed in this section.

Under 35 U.S.C. § 102, "[a] claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently described in a single prior art reference." Thus, unless Defendant can show that Baker '476 teaches every element in claims 1, 2, 6, and 7 of the '802 Patent, its allegation of invalidity fails.

Baker '476 teaches, "compositions and methods for decreasing the infectivity, morbidity, and rate of mortality associated with a variety of pathogenic organisms and viruses." (Abstract.) It also teaches, "methods and compositions for decontaminating areas colonized or other wise infected by pathogenic organisms and viruses." *Id.* It further teaches, "methods and compositions for decreasing the infectivity of pathogenic organisms in foodstuffs." *Id.*

The compositions disclosed and taught in Baker '476 are nanoemulsions. A nanoemulsion is defined as an oil-in-water emulsion with mean droplet diameters ranging from 50 to 1000 nm, with the average being 10 to 500 nm. Stability is achieved by using suitable materials known as emulsifying agents. Actually, nanoemulsion technology¹¹ has been around for at least sixty years.¹² In Baker '476, the nanoemulsion itself serves as an adjuvant delivery system. It has been demonstrated that with the help of a nanoemulsion as a delivery system, retention time of a drug or biopharmaceutical in the body can be increased. Thus, a small amount of an active compound (drug or biopharmaceutical) is required for its therapeutic action.

The asserted claims of the '802 Patent appear in this brief on Page 3, *supra*. In analyzing whether the asserted claims of the '802 Patent are taught by Baker '476, one must examine whether Baker '476 teaches every element of the '802 Patent's asserted claims. Baker '476 would be required to teach:

1. a composition that forms a thin film when applied to a surface;
2. the composition is applied to the skin or tissue of a person's nasal passages;

¹¹ The terms, "nanoemulsions" and "microemulsions" are synonymous.

¹² Schulman JH, Stoeckenius W, and Prince JM, "Mechanism and Formation and Structure of Micro Emulsions By Electron Microscopy," J. Phys. Chem. 1959, 63, 10, 1677-1680, Publication Date: October 1, 1959.

3. the composition contains both a cationic agent and a biocidic agent;
4. the adhesion of the composition is adjusted by varying the ingredients so that the thin film sticks to the skin or tissue of the person's nasal passages;
5. the composition electrostatically attracts harmful particulate matter to the thin film;
6. the adhesion and cohesion¹³ of the composition are adjusted such that the harmful particles are held in place by the thin film.
7. the composition's thin film holds the harmful particles attracted to it in place so that they do not dislodge;
8. the composition provides adequate impermeability to prevent the harmful particles from contacting or penetrating the nasal mucosa;
9. the composition inactivates the particulate matter and renders it harmless; and
10. the composition electrostatically inhibits the harmful particles from infecting the person through nasal inhalation.

Based on the Federal Circuit's decision in *Verdegaal Bros v. Union Oil Co. of California.*, 824 F.2d 628, 631 (Fed. Cir. 1987), if Baker '476 fails to teach any of the 10 attributes *supra* (contained in the asserted claims), the asserted claims of the '802 Patent cannot be invalid by anticipation under 35 U.S.C. § 102. An analysis of the 10 attributes follows.

1. A composition that forms a thin film when applied to a surface is taught by Baker '476 at ¶¶ [0019] and [0206]. This is recited in the preambles of claims 1 and 2 of the '802 Patent.

¹³ Cohesion is a property of a substance where like molecules stick together; It can be observed in a thick viscous material. Here, two similar materials stick together. Adhesion is a property of a substance where unlike molecules stick together. Here, two dissimilar materials stick together.

2. The composition being applied to the skin or tissue of a person's nasal passages is taught in Baker '476 at ¶¶ [0023], [0089], and [0189]. This is recited in the preambles of claims 1 and 2 of the '802 Patent.
3. The composition containing both a cationic agent and a biocidal agent is taught throughout Baker '476. This is recited in the preamble of claim 2 of the '802 Patent.
4. The adhesion of the composition being adjusted by varying the ingredients so that the thin film sticks to the skin or tissue of the person's nasal passages *is not expressly taught anywhere in Baker '476*. The '476 Patent Application is silent about this element, which is recited in Elements (b) of claims 1 and 2 of the '802 Patent.

Since Baker '476 is silent regarding this element, one must examine whether adhesion to the skin or tissue of the person's nasal passages is taught inherently in the application. It has already been established that Baker '476 teaches that the composition forms a thin film on surfaces. However, there is no indication of how well the composition sticks to the nasal mucosa or whether the adhesive properties of its ingredients are adjusted to prevent the nanoemulsion from rapidly dripping out of the user's nose. Adjusting the adhesion of the thin film is an activity that must be performed by a formulator

varying the composition's ingredients. There is no indication that this activity ever took place.

5. Baker '476 is silent regarding the composition electrostatically attracting harmful particulate matter to the thin film. This is recited in Elements (a) of claims 1 and 2 of the '802 Patent. **This element is not expressly taught anywhere in Baker '476.**

Since Baker '476 is silent regarding this element, one must examine whether this element is inherent within its teachings. Baker '476 teaches the presence of cationic agents in its compositions. Cationic agents are known to create a positive electrostatic charge when applied to a surface, such as at a person's nostrils. This property creates a positively charged electrostatic field around the nose. It is also known the most airborne bacteria, viruses, and fungi (*i.e.*, harmful particles) are negatively charged. Thus, it is an inherent property of the compositions that the negatively charged airborne harmful particles will be attracted positively charged thin film. **This is an inherent property of the composition. However, there is no indication that advantage was taken of this inherent property in furtherance of the invention of Baker '476.** Electrostatic attraction of harmful particular matter was never utilized by Baker.

6. The adhesion and cohesion of the composition being adjusted such that the harmful particles are held in place by the thin film **is not expressly taught anywhere in Baker '476**. This is a part of the "hold" function of Elements (b) of claims 1 and 2 of the '802 Patent. The '476 Patent Application is silent about this element.

Since Baker '476 is silent regarding this element, one must examine whether the particles being held in place by the thin film is taught inherently in the application. **This is not an inherent property of the compositions taught in Baker '476**. Moreover, adjusting the adhesion and cohesion of the thin film is an activity that must be performed by a formulator varying the composition's ingredients. There is no indication that this activity ever took place.

7. Baker '476 is silent regarding the composition's thin film holding the harmful particles attracted to it in place so that they do not dislodge **is not expressly taught anywhere in Baker '476**. This is part of the "hold" function in Elements (b) of the '802 Patent.

Since Baker '476 is silent regarding this element, one must examine whether the particles being held in place by the thin film and not dislodging is taught inherently in the application. **This is not an inherent property of the compositions taught in Baker '476**.

8. Baker '476 is silent regarding whether the composition provides adequate impermeability to prevent the harmful particles from contacting or penetrating the nasal mucosa. This is recited in Element's (b) in claims 1 and 2 of the '802 Patent. Neither of the terms "permeability" nor "impermeability" are mentioned in Baker '476. **This element is not taught expressly in Baker '476.**

In its Markman Order (ECF 53), this Court adopted Plaintiff's claim construction where the term **adequate impermeability** "refers to the thin film holding harmful particles in place and inhibiting them from penetrating the thin film and contacting the skin or tissue of an individual's nasal passages. This is done by varying the concentration of ingredients . . . [,]thereby adjusting the adhesion and cohesion of the thin film."

Adequate impermeability is not an inherent property of the compositions of Baker '476, nor does Baker '476 teach anything remotely connected to Element (b) of the '802 Patent's claim either expressly or inherently.

9. That the composition inactivates the particulate mater and renders it harmless is taught throughout Baker '476.

10. At first glance, it would appear that Baker '476 teaches that the composition electrostatically inhibits the harmful particles from infecting the person through nasal inhalation. Defendant would argue that Baker '476 expressly teaches that the "invention relates to methods and compositions for decreasing the infectivity of pathogenic organisms," (Baker '476, Abstract) and that electrostatic attraction of harmful particles to the composition is an inherent property of the composition.

However, prosecution history estoppel forces a different definition onto the term, "electrostatically inhibiting." Submitted herewith as Exhibit 4 is the USPTO office action of August 25, 2011 for U.S. Patent Application No. 12/467,271.¹⁴ As originally submitted, the preamble of claims 1 and 2 used the phrase, "electrostatically **preventing** harmful particulate matter from infecting an individual through nasal inhalation."¹⁵ In Exhibit 4, the Examiner rejected the claims under 35 U.S.C. § 112, First Paragraph "because the specification, while being enabled for, at the most, inhibition of infections, does not reasonably provide enablement for the prevention of the same." (*Id.* Page 2.)

¹⁴ The '802 Patent issued from U.S. Patent Application No. 12/467,271 after allowance.

¹⁵ Emphasis added.

Here, the objective truth of the statement that an infection, which is taken to mean the introduction of an infectious agent through the outside of a given host and into the system of such host, ... , would require that the exterior system of the host to be completely blocked so as to preclude any infectious material passing through such system and arriving within the system of the host.

*In reading the present specification as a whole, it appears the tenor thereof is that infections, whether they cause a pathology or not may be **inhibited**¹⁶ rather than be prevented. The former allowing at least one infectious material to pass into the system of the host rather than the latter which indicates that not even one of the infectious material is allowed to infect, i.e., pass into the system of the host. (Id. at Page 3.)*

The USPTO Examiner stated that the rejection could be overcome by changing the word, "preventing" to "inhibiting." The Applicant amended the claims according to the Examiner's recommendation, and the application was allowed to issue as the '802 Patent.

In its Markman Order (ECF 53), this Court adopted Plaintiff's construction of the term, "electrostatically inhibiting." *Id.* at Page 15.

The Court stated:

Plaintiff suggested “electrostatically inhibiting” be construed as referring to a “formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped, held thereto, and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless.” (Id. at Page 11.)

¹⁶ Emphasis supplied.

The term “electrostatically inhibiting” refers to one of the formulation’s key functions: using an electrostatic field to trap and neutralize harmful particles. It references both the electrostatic means by which the formulation operates and the aim of that formulation. The claim refers to the function as a “method” for “inhibiting harmful particulate matter,” and then the claim describes the three steps necessary for carrying out the inhibition: attracting the particulate matter, holding it in place, and “inactivating” it. (Id. at Page 12)

*The prosecution history of the “802 patent also supports adoption of Plaintiff’s proposed construction. The originally drafted patent used the language “electrostatically preventing” rather than “electrostatically inhibiting.” ... The patent examiner recommended changing that language to “electrostatically inhibiting” because the term “electrostatically preventing” did not “enable any person skilled in the art to which it pertains ... to make and use the invention commensurate in scope with the[] claims.” In other words, the prosecution examiner recommended the term “electrostatically inhibiting” be employed so that a person of ordinary skill in the art of pharmaceutical formulation could effectively use the technology. And “when a word is changed during prosecution, the change tends to suggest that the new word differs in meaning in some way from the original word.” *Ajimoto Co., Inc. v. Int’l Trade Comm’n*, 932 F.3d 1342, 1351 (Fed. Cir. 2019). The patent examiner’s recommended change thus favors Plaintiff’s proposed construction because it reflects a definite meaning of the term “electrostatically inhibiting” that enables a person skilled in the art to use the patented technology. (Id. at Page 13)*

Thus, this Court ruled that, "electrostatically inhibiting" incorporates all three elements, (a), (b), and (c) of claims 1 and 2.

As was argued *supra*, Plaintiff admits that Baker '476 expressly teaches (1) its compositions form a thin film when applied to a surface; (2)

some of its compositions are applied to the skin or tissue of a person's nasal passages; (3) its compositions contain both a cationic agent and a biocidic agent; and (9) its compositions inactivate harmful particulate matter and renders it harmless.

Baker '476 does not expressly teach (5) the composition electrostatically attracts harmful particulate matter to the thin film. However, considering that the composition containing a cationic agent produces a positively charged electrostatic field and that most harmful particles are negatively charged, the composition has the inherent potential of electrostatically attracting said harmful particles. Yet, Baker '476 does not teach or suggest making use of this inherent property anywhere in its disclosure or that it was even aware of it.

Now, Baker '476 does not expressly teach nor is it inherent that (4) the adhesion of the composition is adjusted by varying its ingredients; (6) the cohesion of the composition is adjusted by varying its ingredients; (7) the composition holds the harmful particles in place so that they do not dislodge; and (8) the composition provides adequate impermeability to prevent the harmful particles from contacting the nasal mucosa.

Moreover, Baker '476 does not expressly teach nor is it inherent therein that (10) the composition electrostatically inhibits the harmful

particles from infecting the person through nasal inhalation, as the term "electrostatically inhibiting" was interpreted by both the USPTO and this Court.

Therefore, because not all of the elements of the asserted claims of the '802 Patent are present in the disclosure of Baker '476, the asserted claims of the '802 patent cannot be anticipated by Baker '476 under 35 U.S.C. § 102.

On page 37 of its brief supporting its Motion for Summary Judgment, Defendant stated, "Dr. Amiji has provided unrebutted testimony that the 'HOLD' element of the asserted claims is inherently disclosed by Baker, *i.e.*, it is the 'natural result' flowing from use of the compositions disclosed by Baker. First, he explains that the three functions of 'catch, hold and kill' are 'not performed by three separate ingredients. Benzalkonium chloride as disclosed in Baker '476 imparts positive charge that can 'CATCH,' 'HOLD,' and 'KILL.'"

Respectfully, Dr. Amiji is wrong. Benzalkonium chloride alone cannot cause changes to the adhesive and cohesive properties of the composition, nor can it render the composition adequately impermeable. That can only be done by a formulator adjusting the composition's

ingredients (*e.g.*, a thickener, a binder, a surfactant, *etc.*). This is expressly stated in elements (b) of both claims 1 and 2 of the '802 Patent.

Plaintiff's Expert Report of Edward A/ Lemmo, Ph.D. Responsive to and in Rebuttal of Defendant's Opening Expert Report of Mansoor M. Amiji is submitted herewith as Exhibit 5. This report is responsive to Dr. Amiji's opening report on patent invalidity. On pages 6 to 9 of Exhibit 5, Dr. Lemmo explains the "hold" function and why it is of critical importance to the '802 Patent's formulations. This function is not accomplished by benzalkonium chloride alone. Benzalkonium chloride only creates a positive electrostatic charge and provides biocidal action. It does not affect the adhesion and cohesion of the composition, nor can it make the composition, once applied, adequately impermeable. This is not taught in Baker '476, nor is it an inherent property therein.

Defendant's expert, Amiji, alleges that because BlueWillow's NanoBio® Protect product is described in Baker '476, all of the properties of NanoBio® Protect are necessarily inherent in the disclosure of Baker '476. However, the NanoBio® Protect product was formulated for sale sometime around the year 2020. Even though the formulation may have followed the general outlines of Baker '476, it is not known what adjustments were made to the formulation that may not have been disclosed in the patent application

eleven years earlier. The missing elements were not taught in the prior art. The mere fact that NanoBio® Protect infringes on the claims of the '802 Patent cannot be used as proof that the missing elements are inherent.

Defendant has failed to prove patent invalidity by a clear and convincing evidentiary standard. Summary judgment of patent invalidity should not be granted.

V. CONCLUSION

Plaintiff has shown that there is a genuine dispute as to material facts related to Defendant's allegations of non-infringement of BlueWillow's NanoBio® Protect product over the asserted claims of the '802 Patent. Plaintiff has also shown that there is a genuine dispute as to material facts related to invalidity of the asserted claims of the '802 Patent based on anticipation by Baker '476 under 35 U.S.C. § 102. All of Plaintiff's claim construction arguments were adopted by this Court in its Markman Order. Defendant failed to prove patent invalidity by a clear and convincing evidentiary standard. In addition, Plaintiff has shown that it is entitled to damages as a matter of law by statute under 35 U.S.C. § 284 as well as Fed. R. Civ. P. 54(c). Plaintiff will not rely on expert testimony to prove damages. In addition, Defendant's sales information was delivered to Plaintiff's counsel after close of fact discovery even though it was requested

earlier by Plaintiff. Plaintiff presented estimated calculations of lost profits to the mediator with instructions to deliver it to Defendant's counsel. Defendant's sales information unnecessarily remains under seal to this day. Plaintiff's counsel cannot seek help from Trutek personnel for exact calculations of lost profits. Furthermore, Plaintiff will prove by fact testimony that the packaging for all of its NasalGuard® products sold in the United States since 2012 had the '802 Patent marked thereon.

When deciding a motion for summary judgment, "courts are required to view the facts and draw reasonable inferences 'in the light most favorable to the party opposing the [summary judgment] motion.'" *Scott v. Harris*, 550 U.S. at 377. Considering the arguments presented *supra*, Plaintiff respectfully requests that this Court deny Plaintiff's Motion for Summary Judgment.

Dated: June 1, 2023

Respectfully submitted,

/s/ Stanley H. Kremen
Stanley H. Kremen
4 Lenape Lane
East Brunswick, NJ 08816
(732) 593-7294 Tel.
(732) 312-5218 Fax.
shk@shk-dplc.com

Attorney for the Plaintiff

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender
neutral fictitious names, and ABC
CORPORATION 1 through 10
(fictitious names).

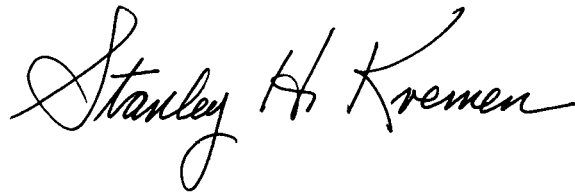
Defendants.

CIVIL ACTION No. 4:21-cv-10312

Hon. F. Kay Behm

CERTIFICATE OF SERVICE

Undersigned hereby states that on June 1, 2023, the attorney for Plaintiff caused the foregoing document to be served upon all counsel of record, via electronic service.



Stanley H. Kremen
4 Lenape Lane
East Brunswick, NJ 08816
(732) 593-7294 Tel.
(732) 312-5218 Fax.
shk@shk-dplc.com

Attorney for the Plaintiff